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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,797	11/23/2001	George Jackowski	2132.084	5616

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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,797	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 41 is/are rejected.
- 7) ☒ Claim(s) 42 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>see attached</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/12/02</u> | 6) <input type="checkbox"/> Other: _____ |

Handwritten signature/initials

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed 18 November 2004 is acknowledged (Paper filed 2/22/05). In the amendment filed therein claim 1 was modified, claims 2-38 were canceled, and new claims 39-46 were added. Currently, claims 1 and 39-46 are pending and under consideration.

Election/Restrictions

2. Claim 1 is directed to an allowable product (An isolated biopolymer consisting of SEQ ID NO:1 or SEQ ID NO:2 diagnostic for Alzheimer's disease). Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 39-46 (previously claims 3-38), directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, claims 39-46 are now subject to being rejoined. Claims 1 and 39-46 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on 11/18/04 is hereby withdrawn.

3. Objections and/or rejections of record not reiterated below have been withdrawn.

REMARKS

Information Disclosure Statement

4. Applicants have requested a copy of the PTO-1449 form filed March 12, 2002. It has been provided with the instant application.

Prior Amendments

5. Applicant's have noted that the Office has not entered two documents previously submitted by Applicant's. A preliminary Amendment filed on March 4, 2002 and a Response to a Notice to Comply mailed on August 16, 2002. Examiner has reviewed the prosecution history and cannot locate the cited documents. Applicant is invited to re-submit the documents to complete the record.

REJECTIONS WITHDRAWN

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 2 are withdrawn from rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicant contends that the modification to the specification clearly set forth enablement of the instant disclosure. This argument has been carefully considered and found persuasive. Accordingly the rejection is withdrawn.

Double Patenting

7. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1 and 2 are withdrawn from provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of copending Application No. 09/993,304. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. SEQ ID NO:1 of application number 09/993,304 is the same as SEQ ID NO:2 in the instant application.

Response to Argument

Applicant contends that the claims in application number 09/993,304 have been amended to on SEQ ID NO:3 and therefore does not conflict with the instantly claimed subject matter. This argument was carefully considered and found persuasive. Accordingly the rejection is withdrawn.

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Interview Summary

8. Examiner phoned Applicant to correct 112, 2nd issues. However, the Applicant could not be reached. See attachment. Therefore the following rejections are presented.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Objections

9. Claims 42 and 44 are objected to because of the following informalities: Claim 42 utilizes acronyms. They should be defined in their first instance to convey Applicant's intended meaning. In claim 44 "an" should be in front of antibody in (b). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 39 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 39 is vague and indefinite because it is unclear as to what a "maximized elucidation" will encompass. Will the sample be profiled or not? It is not clear what other process is intended to maximize the sample profiling. It is suggested that "maximize" be removed from the claim language in order to obviate this rejection. Please explain/correct.

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B. In claim 39 step c), the comparison of “characteristic profiles” is vague and indefinite because it is not clear what characteristic is being assessed. If the mass spectrum profiles are being compared, then the claim should clearly set forth this limitation.

C. Claim 41 is vague and indefinite in utilizing the phrase “blood products”. Because the term is not defined in the disclosure the metes and bounds cannot be determined. Is it applicants’ intent to claim any material containing blood, any product useful in blood analyses, or any product derived from blood? Please clarify.

11. For reasons aforementioned, no claims are allowed.

Allowable Subject Matter

12. Claim 1 is allowed. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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5/31/05



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